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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HALVORSON, MARK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,254	KIENER ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-30, drawn to a method of treating a non-neoplastic hyperproliferative cell or excessive cell accumulation disorder in a patient, classified in class 514, subclass 2.

   II. Claims 31, 32, drawn to a method of diagnosing a non-neoplastic hyperproliferative cell or excessive cell accumulation disorder, classified in class 435, subclass 7.1.

The methods of Groups I and II are materially distinct methods which differ at least in objectives, method steps and reagents. Group I is drawn to a method of treating a non-neoplastic hyperproliferative cell or excessive cell accumulation disorder in a patient. Group II is drawn a method of diagnosing a non-neoplastic hyperproliferative cell or excessive cell accumulation disorder. Each of the groups employ different reagents to accomplish different objectives that comprise different method steps. Searching all of the groups with all of the different objectives, method steps, and reagents would invoke a high burden of search.

2. This application contains claims directed to the following patentably distinct inventions.

Group I is subject to election of at least one of the disclosed inventions.

Claim 1 is drawn to methods using multiple disorders that fails the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Claim 1 is a generic claim which include a Markush-type plurality of alternatively usable substances or members. A Markush-type claim can include independent and distinct inventions. In this case these different disorders are considered to be biologically independent because each is represented by unique features such as etiology and treatment.

(i) Claim 1 is generic to a plurality of disclosed patentably distinct inventions of disorders wherein the disorders are (a) **epithelial cell disorder** or (b) **endothelial cell disorders**.

(i)(a)(1). Invention (a) above is further subject to restriction because claim 2 is generic to a plurality of disclosed patentably distinct inventions comprising the method of the instant invention whereby the epithelial cell disorder comprises: (a) asthma, (b) chronic pulmonary obstructive disease (c) lung fibrosis (d) asbestosis, (e) IPF, (f) DIP, (g) UIP, (h) kidney fibrosis, (i) liver fibrosis, (j) other fibroses, (k) bronchial hyper responsiveness, (l) psoriasis, and (m) seborrheic dermatitis.

(i)(a)(2). Invention (a) above is further subject to restriction because claim 3 is generic to a plurality of disclosed patentably distinct inventions comprising the method of the instant invention whereby the pathology causing cell phenotypes are (a) secretion of mucin, (b) differentiation of an EphA2-expressing cell into a mucin-secreting cell, (c) secretion of inflammatory factors, (d) epithelial cell proliferation or (e) endothelial cell hyperproliferation.

(i)(b)(1). Invention (b) above is further subject to restriction because claim 2 is generic to a plurality of disclosed patentably distinct inventions comprising the method of the instant invention whereby the endothelial cell disorder comprises: (a) restenosis, (b) hyperproliferative vascular disease, (c) Behcet's Syndrome, (d) atherosclerosis, and (e) macular degeneration.

(i)(b)(2). Invention (b) above is further subject to restriction because claim 6 is generic to a plurality of disclosed patentably distinct inventions comprising the method of the instant invention whereby the pathology causing cell phenotypes are (a) increased cell migration, (b) cell volume, (c) secretion of extracellular matrix molecules, (d) secretion of matrix metalloproteinases, or (e) endothelial cell hyperproliferation.

Group I is subject to election of at least one of the disclosed inventions.

Claim 1 is drawn to methods using multiple effects that fails the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Claim 1 is a generic claim which include a Markush-type plurality of alternatively usable substances or members. A Markush-type claim can include independent and distinct inventions. In this case these different disorders are considered to be biologically independent because each is represented by unique features such as etiology and treatment.

(ii) Claim 1 is generic to a plurality of disclosed patentably distinct inventions of disorders wherein the effects of administration of an EphA2 agonist are (a) **increase in EphA2 phosphorylation (claim 14)** or (b) **decreases EphA2 expression (claim 15)**.

Group I is subject to election of at least one of the disclosed inventions.

Claim 1 is drawn to methods using multiple agents that fails the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where

compounds included within a Markush group share a substantial structural feature disclosed as being essential to that utility.

Claim 1 is a generic claim which include a Markush-type plurality of alternatively usable substances or members. A Markush-type claim can include independent and distinct inventions. In this case these different disorders are considered to be biologically independent because each is represented by unique features such as etiology and treatment.

(iii) Claim 1 is generic to a plurality of disclosed patentably distinct inventions of agents wherein the agents are (a) **one or more immunomodulatory agents (claim 27)** or (b) **one or more anti-viral agents (claim 29)**.

Group 1 is further subject to election of at least one of the disclosed inventions.

Claims 7 and 8 are drawn to methods using multiple EphA2 agents that fails the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group share a substantial structural feature disclosed as being essential to that utility.

Claim 7 and 8 are generic claims which include a Markush-type plurality of alternatively usable substances or members. A Markush-type claim can include independent and distinct inventions. In this case these different molecular entities are considered to be structurally, chemically and biologically independent because each is represented by a unique structural feature.

(iv) Claims 7 and 8 are generic to a plurality of disclosed patentably distinct inventions wherein the agents are (a) antibody, (b) small molecule agonists, (c) enzymatic activity antagonists, (d) ribozymes, (e) siRNA or (f) EphA2 antisense molecules.

Group I is further subject to election of at least one of the disclosed inventions.

Claim 17 is drawn to methods using multiple pathology causing cell phenotypes that fails the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Claim 17 is a generic claim which include a Markush-type plurality of alternatively usable substances or members. A Markush-type claim can include independent and distinct inventions. In this case these different disorders are considered to be biologically independent because each is represented by unique features such as etiology and treatment.

(v). Claim 17 is generic to a plurality of pathology causing cell phenotypes wherein the phenotypes are (a) secretion of mucin, (b) differentiation of an EphA2-expressing cell into a mucin-secreting cell, (c) secretion of fibronectin, (d) secretion of inflammatory factors, (e) epithelial cell hyperproliferation or (f) endothelial cell hyperproliferation.

Group I is further subject to election

Claim 20 is drawn to methods using multiple pathology causing cell phenotypes that fails the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Claim 20 is a generic claim which include a Markush-type plurality of alternatively usable substances or members. A Markush-type claim can include independent and distinct inventions. In this case these different disorders are considered to be biologically independent because each is represented by unique features such as etiology and treatment.

(vi). Claim 20 is generic to a plurality of disclosed patentably distinct inventions comprising the method of the instant invention whereby the pathology causing cell phenotypes are (a) cell migration, (b) cell volume, (c) secretion of extracellular matrix molecules, (d) secretion of matrix metalloproteinases, or (e) endothelial cell hyperproliferation.

Group II is further subject to election of at least one of the disclosed inventions.

Claim 33 is drawn to methods using multiple disorders that fails the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Claim 33 is a generic claim which include a Markush-type plurality of alternatively usable substances or members. A Markush-type claim can include independent and distinct inventions. In this case these different disorders are considered to be biologically independent because each is represented by unique features such as etiology and treatment.

(vii) Claim 33 is generic to a plurality of disclosed patentably distinct inventions of disorders wherein the disorders are (a) asthma, (b) chronic pulmonary obstructive disease (c) lung fibrosis (d) bronchial hyper responsiveness, (d) psoriasis, (e) seborrheic dermatitis, (f) cystic fibrosis, (g) restenosis, (h) hyperproliferative vascular disease, (i) Behcet's Syndrome, (j) atherosclerosis, and (k) macular degeneration.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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571-272-6539

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER